

## REMARKS/ARGUMENTS

This is in response to the Office Action of November 1, 2007 and the Advisory Action of April 11, 2008. In that Office Action, Claims 1, 4-12, and 14-27 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,746,215 to Manjarrez.

Claims 13 and 28 were rejected under 35 USC 103(a) as being obvious over Manjarrez as modified by U.S. Patent No. 6,908,455 to Hajianpour.

By this Amendment, independent Claims 1 and 11 and dependent Claim 7 have been amended. Further by this Amendment, dependent Claims 4-6, 8, 22-23 and 25 have been canceled.

Claim 1, as amended, is directed to a needle protector for use with a needle assembly that includes a flexible plastic tube attached to a needle hub and a needle mounted on the hub. The housing of the needle protector is defined by a plurality of side walls. The housing includes an open distal end and a proximal end. The proximal end has an end wall defining a fully enclosed aperture. The enclosed aperture is a multiple profile window adapted to selectively slidably receive and retain the tubing. At least one of the side walls includes a flexible retaining member located a distance from the distal end for retaining the hub of the needle assembly. Further, at least one of the side walls has an internal groove that extends axially from the distal end to the proximal end.

Claim 11, as amended, is directed to a needle protector for use with a needle assembly that includes a flexible plastic tube attached to a needle hub with a rib that extends outwardly and a needle mounted on the hub. The housing of the needle protector is defined by a plurality of side walls. The housing includes an open distal end and a proximal end. The proximal end has an end wall defining a fully enclosed

aperture. The enclosed aperture defines a multiple profile window adapted to selectively slidably receive and retain the tubing. At least one of the side walls includes a flexible retaining member adapted for contacting the hub of the needle assembly and located a sufficient distance from the distal end such that the piercing end is completely enclosed in the interior chamber. Further, at least one other of the side walls has an internal groove that extends axially from the distal end to the proximal end.

Regarding Claim 1, it is the position of the Patent Office that Manjarrez discloses "side walls having a retaining member (72)." Manjarrez identifies reference number 72 as an "end ramp section" (column 3, lines 53-54), an "end" (column 4, line 29) and a "distal end 72 of housing 22" (column 4, line 38). Manjarrez, however, does not disclose that 72 is a retaining member that is spaced a sufficient distance from the distal end such that the piercing end is fully enclosed within the interior chamber of the needle housing. Manjarrez does disclose a rigid permanent lock rib 84 on a side wall that engages a lock tab 86 on the needle holder 50 to retain the needle in the housing in a fully retracted position (column 4, lines 57-60). However, by contrast, Amended Claim 1 recites a side wall that includes a flexible retaining member that engages the hub. Having the flexible retaining member on the side wall minimizes the possibility of breaking the retaining member off during assembly, shipping or handling. The lock tabs disclosed by Manjarrez project out from the needle and are therefore vulnerable to being broken or damaged during assembly, shipping or handling. Manjarrez does not discuss the need for a side wall that includes a flexible retaining member, and for that reason does not disclose or suggest one.

Also regarding Claim 1, it is the position of the Patent Office that Manjarrez discloses "ledges (edges of 54) defining an axial groove." Manjarrez identifies

reference number 54 as "channel 54" (column 3, lines 45 and 53) and as "longitudinal slot 54" (column 4, lines 11-12). The area defined within the edges of channel 54 is actually a slot that is open from the internal cavity of the housing through to the outside of the housing. By contrast, the axial groove recited in Amended Claim 1 is an internal groove (open only towards the interior chamber) and is not an external slot as disclosed in Manjarrez. Moreover, the axial groove is not defined by ledges as is the case in Manjarrez. The axial groove of Amended Claim 1 is provided to receive and accommodate the rib on the needle hub in the event that the needle hub is inverted as it enters the needle protector. The axial groove allows the needle hub to be retracted, even in the inverted position, into the needle protector without interference [00033]. By contrast, Manjarrez discloses that channel or longitudinal slot 54 is a means by which the actuating button 52 is able to move forward to make the device in a condition for use (column 3, lines 51-54; column 4, lines 10-12). In Manjarrez, inversion of the needle is not possible as the needle is fixed to the external actuating button. Thus, Manjarrez has no appreciation for needing an axial groove to allow the needle hub to be retracted in the inverted position, and for that reason does not disclose or suggest one.

Further regarding Claim 1, it is the position of the Patent Office that Manjarrez discloses "a multiple profile window having a smaller and larger cross sections." Manjarrez discloses a tube receiving slot that is not fully enclosed by the end wall, but instead has a gap in the outer perimeter of the end wall in which the tubing can be laterally displaced (Fig. 11). Once laterally displaced through the gap in the end wall, the tubing would not be retained and instead the tubing would be able to hang freely. By contrast, Amended Claim 1 recites a multiple profile window that defines a fully enclosed aperture in the end wall of the proximal end such that the tubing cannot be

laterally displaced out of the window. Providing a multiple profile window of Amended Claim 1 maintains the tubing positioned through the proximal end and further provides one profile that allows the tubing to slide freely and yet be contained by the housing, and another profile that holds the tubing in place. Manjarrez has no appreciation for the desirability of holding the tubing and for that reason does not disclose or suggest one.

Therefore, Applicants submit that for these reasons independent Claim 1 is not anticipated by Manjarrez.

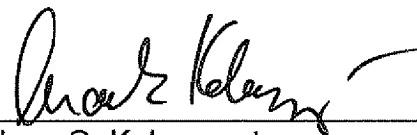
Regarding Claim 11, it is the position of the Patent Office that Manjarrez discloses "...guiding ledges (edges of 54) defining an axial groove..." However, the area defined within the edges of 54 is actually a slot that is open from the internal cavity of the housing through to the outside of the housing. In contrast, the axial groove recited in Claim 11 is an internal groove (open only towards the interior chamber) and is not an external slot as disclosed in Manjarrez. Moreover, the axial groove is not defined by guiding ledge(s) as is the case in Manjarrez. As discussed above, the axial groove of Claim 11 is provided to receive and accommodate the rib on the needle hub in the event that the needle hub is inverted as it enters the needle protector. The axial groove allows the needle hub to be retracted, even in the inverted position. In contrast, Manjarrez discloses that channel or longitudinal slot 54 is a means by which the actuating button 52 is able to move forward to make the device in a condition for use (column 3, lines 51-54; column 4, lines 10-12). In Manjarrez, inversion of the needle is not possible as the needle is attached to the external activating button. Thus, Manjarrez has no appreciation for needing an axial groove to allow the needle hub to be retracted in the inverted position, and for that reason does not disclose or suggest one.

Therefore, Applicants submit that for these reasons independent Claim 11 is not anticipated by Manjarrez.

Claims 7, 9-10, 12-21, 24 and 26-28 depend from either independent Claims 1 or 11, and for the reasons set forth above, Applicants submit that dependent Claims 7, 9-10, 12-21, 24 and 26-28 are likewise not anticipated by Manjarrez.

All of the pending Claims 1, 7, 9-21, 24 and 26-28 are believed to be in condition for allowance. Reconsideration and allowance of such claims are respectfully requested.

Respectfully submitted,



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